

Title 19 – HEALTH AND SENIOR SERVICES
Division 10 – Office of the Director
Chapter 33—Hospital and Ambulatory Surgical Center Data Disclosure

PROPOSED RULE

19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers

PURPOSE: This rule establishes procedures for reporting patient abstract data for inpatients and outpatients by hospitals and ambulatory surgical centers to the Department of Health and Senior Services and for the management and dissemination of this data.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) The following definitions shall be used in the interpretation of this rule:

(A) Coinvestigator means any person or organization that applies to the Department of Health and Senior Services to be a coinvestigator of an epidemiological study;

(B) Department means the Missouri Department of Health and Senior Services;

(C) Epidemiological study means research using patient abstract data to understand, promote or safeguard the health of a defined population. No marketing study or study designed to use data on a specific provider shall be considered an epidemiological study;

(D) Inpatient encounter means an encounter which begins with the formal acceptance by hospital or a distinct part of the hospital of a patient who is to receive physician, dentist or allied services while receiving room, board and continuous nursing care. It ends with the termination of the room, board and continuous nursing services, and the formal release of an inpatient from the hospital or the transfer of the patient to a different distinct hospital unit. All significant procedures are to be reported. A significant procedure is one that is surgical in nature; carries a procedural risk; requires specialized training; carries an anesthetic risk such as open procedures, endoscopy procedures, catheterization procedures, pain management procedures, injection procedures such as myelograms, arthrograms, etc.; or is needed for Medicare Severity Diagnosis Related Group (MS-DRG) assignment. Inpatient procedures should be coded according to the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS);

(E) Observation services are those services furnished on a hospital's premises, including use of a bed and periodic monitoring by a hospital's nursing or other staff, which are reasonable and necessary to evaluate an outpatient's condition or determine the need for a possible admission to the hospital as an inpatient. Charges for observation services usually are made on an hourly basis. Observation services usually do not exceed twenty-four (24) hours. However, there is no hourly limit on the extent to which they may be used;

(F) Outpatient encounter refers to patients seen in the emergency room and patients receiving invasive procedures on an outpatient basis. All significant procedures are to be reported. A significant procedure is one that is surgical in nature; carries a procedural risk; requires specialized training; or carries an anesthetic risk such as open procedures, endoscopy procedures, catheterization procedures, pain management procedures, injection procedures such as myelograms, arthrograms, etc. Outpatient procedures should be coded according to the Healthcare Common Procedure Coding System (HCPCS). HCPCS is divided into two principal subsystems, referred to as level I and level II. Level I is comprised of Current Procedural Terminology (CPT-4), and level II is a standardized coding system used to report services not identified by CPT-4 codes.

(G) Public health authority means an agency or authority that is responsible for public health matters as part of its official mandate. Examples of public health authorities include agencies of a state, territory, political subdivision of a state or territory, or an Indian tribe, or persons or entities acting under a grant of authority or contract with a public health authority.

(2) Data which meet the completeness, validity and consistency criteria in subsections (2)(C) and (D) of this rule shall be submitted to the department or to an association or related organization with which the department has a binding agreement to obtain data on a quarterly basis according to the Data Reporting Schedule in Table 1, included herein. Data shall be considered to be submitted when received by the department or the association or related organization prior to the close of business on the scheduled due date. Requests for extensions shall be submitted to the department at least ten working days prior to the due date as listed in Table 1. Extensions to the submittal schedule may be granted for a maximum of thirty (30) calendar days. The facility shall separately request each additional thirty (30) calendar day extension.

Table 1 – Data Reporting Schedule

Quarter	Period of Patient Encounter (Discharge Date)	Date Due
1 st	January 1 – March 31	June 1
2 nd	April 1 – June 30	September 1
3 rd	July 1 – September 30	December 1
4 th	October 1 – December 31	March 1 of the following year

(A) Each facility shall submit to the department, or to an association or related organization with which the department has a binding agreement to obtain data, a single record for each patient discharge, according to the schedule shown in Table 1 – Data Reporting Schedule, included herein. For a patient with multiple discharges, a facility shall submit a separate data record for each individual discharge. For a patient with multiple billing claims, a facility shall consolidate the multiple billings into a single discharge data record for submission after the patient's discharge.

(B) The patient abstract data shall include the data elements and conform to the specifications listed in the document entitled "Patient Abstract System File Specifications" dated October 27, 2014, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at <http://health.mo.gov/data/pdf/paslayout.pdf>, for all records with a discharge date of October 1, 2015 or later. This rule does not incorporate any subsequent amendments or additions. The patient abstract data shall be submitted electronically through the department's online system or by any other mutually agreed upon method. The Department of

Health and Senior Services, Bureau of Health Care Analysis and Data Dissemination may be contacted by mail at PO Box 570, Jefferson City, MO 65102-0570 or by telephone at (573)751-6272.

(C) Each data element shall have an acceptable code in at least ninety-nine percent (99%) of the records. Each data element shall be missing or unknown in less than one percent (1%) of records.

(D) The following data elements shall be consistent within at least ninety-nine percent (99%) of individual records:

1. Date of birth, sex, diagnoses, External Cause of Morbidity (ECM) code, Present On Admission (POA) ECM code, ECM Place of Occurrence code, ECM Activity code, ECM Status code, procedure(s);
2. State of residence, zip code, county; and
3. Admission date, procedure date(s), discharge date, date of birth.

(3) After the due date listed in Table 1, included herein, providers shall be allowed fifteen (15) working days from the date of notification by the department to correct identified data submission errors. Revisions of data originally filed shall contain the entire quarterly dataset.

(4) Providers may submit the required data to the department through an association or related organization with which the department has a binding agreement to obtain data. The association or related organization shall provide to the department by January 1 of each year a list of providers for whom it will submit data. Providers selecting this option are responsible for ensuring that the data meet the quality criteria of completeness, validity and consistency in subsections (2)(C) and (D) of this rule. Data shall be submitted to the association or related organization according to the time schedule in section (2), Table 1, included herein, of this rule. The association or related organization is responsible for ensuring that the data are provided to the department using one of the submission methods specified in section (2)(B) of this rule and conform to the specifications listed in the document entitled "Patient Abstract System File Specifications" dated October 27, 2014, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at <http://health.mo.gov/data/pdf/paslayout.pdf>, for all records with a discharge date of October 1, 2015 or later. This rule does not incorporate any subsequent amendments or additions. The association shall submit provider data to the department within thirty (30) days following the due date listed in section (2), Table 1, included herein, of this rule. The association or related organization may submit a request for extension, as described in section (2) of this rule, on behalf of a facility.

(5) Providers may submit data directly to the department or through a third party acting as their agent, other than one with which the department has a binding agreement. Providers selecting this option shall be responsible for ensuring that all data specifications conform to the requirements listed in section (2) of this rule. The third party agent may submit a request for extension, as described in section (2) of this rule, on behalf of a facility.

(6) The department may develop and publish reports pertaining to individual hospitals and ambulatory surgical centers. The reports may include information on charges and quality of care indicators. The reports and the data they contain shall be public information and may be released on electronic media. The department shall make the reports and data available for a reasonable charge based on incurred costs.

(7) The department shall use statistical rules to minimize random fluctuations and extreme outliers in publishing provider-specific reports on charges. The rules may vary by publication but average charges based on fewer than twenty (20) events shall not be published.

(8) The department may develop summary reports upon request which do not directly or indirectly identify patients, physicians or providers. The reports shall be public information. The department shall make the reports available for a reasonable charge based upon incurred costs.

(9) The department shall store the patient abstract data in password-protected directories to limit access of the data only to employees of the department who are designated to have access to the files.

(10) The department may release patient abstract data to a public health authority to assist the agency in fulfilling its public health mission. Public health authorities shall follow the same guidelines used by the department when releasing summary reports based on record-level data. Record-level data shall not be rereleased in any form by the public health authority without the prior authorization of the department. Authorization for subsequent release of the data shall be considered only if the proposed release does not identify a patient, physician or provider. The following data elements permit identification of a patient, physician or provider, and shall not be rereleased by a public health authority: patient name; patient Social Security number; any datum which applies to fewer than three (3) patients, physicians or providers; physician number; provider number; and a quantity figure if one (1) hospital or ambulatory surgical center contributes more than sixty percent (60%) of the amount. However, the department may authorize contact with the patient, physician or provider based upon the information supplied. The physician and provider that provided care to a patient shall be informed by the public health authority of any proposed contact with a patient.

(11) The public health authority shall agree to the department's requirements regarding the confidentiality, security, and release of data and shall agree to the review and oversight requirements imposed by the department.

(12) Any person may apply to the department to be a coinvestigator of an epidemiological study using patient abstract data. A research protocol shall be submitted which includes all of the following:

- (A) A description of the proposed study;
- (B) The purpose of the study;
- (C) A description of the data elements needed for the study;
- (D) A statement indicating whether the study protocol has been reviewed and approved by an institutional review board;
- (E) A description of data security procedures, including who shall have access to the data; and
- (F) A description of the proposed use and release of the data.

(13) The director of the department shall appoint a data release advisory committee which may be composed of representatives from the department, the Hospital Industry Data Institute (HIDI) of the Missouri Hospital Association (MHA), and other entities. The advisory committee shall review all research protocols of persons applying to be a coinvestigator of an epidemiological study using patient abstract data. The advisory committee shall make a recommendation to the department whether the coinvestigator protocol should be accepted, accepted with conditions, or rejected. The committee shall consider:

- (A) The review made by the staff of the department;
- (B) Whether the proposed study meets the definition of an epidemiological study;

- (C) The potential for the coinvestigator or any other person to use the data for nonepidemiological purposes;
- (D) The professional expertise of the applicant to conduct the study;
- (E) The appropriateness of the proposed study design;
- (F) The willingness and ability of the applicant to protect the identity of any patient, physician or provider;
- (G) The data security measures and final disposition of the data proposed; and
- (H) Whether the proposed study is relevant to public health in Missouri.

(14) The coinvestigator shall follow the same guidelines used by the department when releasing summary reports based on record-level data. Record-level data released to the coinvestigator shall not be rereleased in any form by the coinvestigator without the prior authorization of the department. Authorization for subsequent release of record-level data or summary reports shall be considered only if the proposed release does not identify a patient, physician or provider. The following data elements permit identification of a patient, physician or provider, and are not to be rereleased by a coinvestigator: patient name; patient Social Security number; any datum which applies to fewer than three (3) patients, physicians or providers; physician number; provider number; and a quantity figure if one (1) hospital or ambulatory surgical center contributes more than sixty percent (60%) of the amount.

(15) The coinvestigator shall agree to the department's requirements regarding the confidentiality, security, and release of data and shall agree to the review and oversight requirements imposed by the department.

(16) The department shall release only those patient abstract data elements to the coinvestigator which the department determines are essential to the study. The National Provider Identifier (NPI) associated with any patient abstract data shall not be released to any coinvestigator. If the research being conducted by a coinvestigator requires a physician number, the department may create a unique number which is not the NPI. The department shall not provide information which links the unique number to the name of the physician.

(17) No epidemiological study conducted with a coinvestigator shall be approved unless the department determines that—

- (A) The epidemiological study has public benefit sufficient to warrant the department to expend resources necessary to oversee the project with the coinvestigator;

- (B) The department has sufficient resources available to oversee the project with the coinvestigator; and

- (C) The data release advisory committee reviewed the study and the director of the department authorized approval.

(18) Public health authorities and coinvestigators receiving data shall be informed by the department of the penalty for violating section 192.067, RSMo.

(19) Any provider which determines that it will be temporarily unable to comply with any of the provisions of sections (1) through (5) of this rule or with the provisions of a previously-submitted plan of correction shall provide the department with written notification of the expected deficiencies and a written plan of correction. This notification and plan of correction shall include the specific reasons why the provider cannot comply with the rule, an explanation of any extenuating factors which may be relevant, the means the provider will employ for correcting the expected deficiency, and the date by which each corrective measure will be completed.

(20) Any provider which is not in compliance with sections (1) through (5) of this rule shall be notified in writing by the department. The notification shall specify the section number and text of the rule in question, the deficiency, and the action which must be taken to be in compliance. The chief executive officer or designee shall have ten (10) working days following receipt of the written notification of noncompliance to provide the department with a written plan for correcting the deficiency. The plan of correction shall specify the means the provider will employ for correcting the cited deficiency and the date that each corrective measure will be completed.

(21) Upon receipt of a required plan of correction, the department shall review the plan to determine the appropriateness of the corrective action. If the plan is acceptable, the department shall notify the chief executive officer or designee in writing and indicate that implementation of the plan should proceed. If the plan is not acceptable, the department shall notify the chief executive officer or designee in writing and indicate the reasons why the plan was not accepted. A revised, acceptable plan of correction shall be provided to the department within ten (10) working days.

(22) Failure of the provider to submit an acceptable plan of correction within the required time shall be considered continued and substantial noncompliance with this rule unless determined otherwise by the director of the department.

(23) Failure of any provider to follow its accepted plan of correction shall be considered continued and substantial noncompliance with this rule unless determined otherwise by the director of the department.

(24) Any provider in continued and substantial noncompliance with this rule shall be notified in writing and reported by the department to its appropriate licensing program within the Division of Regulation and Licensure and the Bureau of Special Health Care Needs, the MO HealthNet Division of the Department of Social Services, and other state agencies that administer a program with provider participation. The department shall notify the agencies that the provider is no longer eligible for participation in a state program or to receive any monies from the state.

(25) Any provider that has been declared to be ineligible to participate in a state program or to receive any monies from the state shall be eligible for reinstatement by correcting the deficiencies and making written application for reinstatement to the Department of Health and Senior Services. Any provider meeting the requirements for reinstatement shall be notified in writing. Those agencies that received a notice pursuant to section (24) of this rule shall be notified by the Department of Health and Senior Services when the provider has come into compliance.

AUTHORITY: section 192.667, RSMo Supp. 2014. Emergency rule filed Nov. 4, 1992, effective Nov. 14, 1992, expired March 13, 1993. Emergency rule filed March 4, 1993, effective March 14, 1993, expired July 11, 1993. Original rule filed Nov. 4, 1992, effective June 7, 1993. Emergency amendment filed April 1, 1993, effective April 11, 1993, expired Aug. 8, 1993. Emergency amendment filed Aug. 10, 1993, effective Aug. 20, 1993, expired Nov. 18, 1993. Amended: Filed April 1, 1993, effective Dec. 9, 1993. Amended: Filed May 15, 1998, effective Nov. 30, 1998. Emergency amendment filed March 1, 2001, effective April 1, 2001, expired Jan. 10, 2002. Amended: Filed April 13, 2001, effective Oct. 30, 2001. Filed: *Original authority: 192.667, RSMo 1992, amended 1993, 1995.*

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions \$36,000 in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed rule with the Missouri Department of Health and Senior Services, Division of Community and Public Health, Harold Kirbey, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*